UNITED STATES DEPARTMENT OF COMMERCE
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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,996,335 was filed on May 6, 1998, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, LOTEMAX™ and ALREX™ (loteprednol etabonate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, the list of Drug Approvals for March 1998 (found at http://www.fda.gov/cder/da/da0398.htm) indicates that the approval on March 9, 1998 of New Drug Application (NDA) No. 20-841 for LOTEMAX™ and the approval on March 9, 1998 of NDA No. 20-803 were approvals of a new dosage form or new formulation of an active ingredient already on the market. However, the approval of NDA No. 20-583, on the same day, also for LOTEMAX™, was indicated as an approval of a new chemical entity. The reason for this inconsistency, and the result thereof, is not clear.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Norman H. Stepno, Esq.
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